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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/753,910	01/02/2001	Stephen W. Pettit	PET-01	2562
34313	7590	05/04/2006	EXAMINER	
ORRICK, HERRINGTON & SUTCLIFFE, LLP IP PROSECUTION DEPARTMENT 4 PARK PLAZA SUITE 1600 IRVINE, CA 92614-2558			FRENEL, VANEL	
		ART UNIT	PAPER NUMBER	
		3626		
DATE MAILED: 05/04/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/753,910	PETTIT, STEPHEN W.	
	Examiner	Art Unit	
	Vanel Frenel	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02 January 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>0122001, 5132002, 12242002, 6232003
982003</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the application filed 01/02/01. Claims 1-20 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al (5,673,944) in view of Effect of Patient reminder/recall interventions on immunizations rates: A review by Peter G. Szilagyi, et al. (JAMA; Chicago: Oct.11, 2000. Vol.284, Iss.14; pg.1820, 8 pgs.).

(A) As per claim 1, Walker discloses a method of tracking immunizations by use of machine-readable communications devices, the method comprising the steps of: attaching a machine-readable communications device on an immunization product package (Col.4, lines 19-28 and 34-37), the communications device comprising machine-readable data including immunization product identification, manufacturer identification, immunization product lot number, and manufacturing date (Col.4, lines 19-28).

Walker does not explicitly disclose entering at least a portion of the machine-readable data read by a machine from the machine-readable communications device on the immunization product package to a computerized immunization-tracking file at an immunization provider location; and entering patient identification and administration date on the immunization-tracking file generally at the time of administration.

However, these features are known in the art, as evidenced by Szilagyi. In particular, Szilagyi suggests that entering at least a portion of the machine-readable data read by a machine from the machine-readable communications device on the immunization product package to a computerized immunization-tracking file at an immunization provider location (See Szilagyi, Page 8, Paragraphs 1-5); and entering patient identification and administration date on the immunization-tracking file generally at the time of administration (See Szilagyi, Page 8, Paragraphs 1-5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Szilagyi within the system of Walker with the motivation of providing patient reminder systems in primary care settings which are effective in improving immunizations rates. Primary care physicians should use patient reminders to improve immunization delivery (See Szilagyi, Page 2, Paragraph 1).

(B) As per claim 2, Szilagyi discloses the method of tracking immunizations comprising the additional step of providing the immunization-tracking file on a network to define a computerized immunization tracking system comprising a plurality of

computerized immunization-tracking files accessible from a plurality of immunization provider locations (See Szilagyi, Page 3, Paragraphs 1-8; Page 8, Paragraphs 1-5).

The motivation for combining the respective teachings of Walker and Szilagyi are as discussed above in the rejection of claim 1, and incorporated herein.

(C) As per claim 3, Szilagyi discloses the method of tracking immunizations wherein the machine-readable data includes immunization dose (Page 4, Paragraphs 1-7).

The motivation for combining the respective teachings of Walker and Szilagyi are as discussed above in the rejection of claim 1, and incorporated herein.

(D) As per claim 4, Szilagyi discloses the method of tracking immunizations wherein an administered dose is entered on the immunization tracking file generally at the time of administration at the immunization provider location (Page 8, Paragraphs 1-3).

The motivation for combining the respective teachings of Walker and Szilagyi are as discussed above in the rejection of claim 1, and incorporated herein.

(E) As per claim 5, Walker discloses the method of tracking immunizations wherein the machine-readable device comprises a bar code attached to the immunization product packaging (Col.4, lines 59-67).

(F) As per claim 6, Walker discloses the method of tracking immunizations wherein the machine-readable device comprises a magnetic strip attached to the immunization product packaging (Col.5, lines 13-67).

(G) As per claim 7, Walker discloses the method of tracking immunizations wherein the machine-readable device comprises a microprocessor attached to the immunization product packaging (Col.2, lines 13-67).

4. Claims 8-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al (5,673,944) in view of Effect of Patient reminder/recall interventions on immunizations rates: A review by Szilagyi, et al. (JAMA; Chicago: Oct.11, 2000. Vol.284, Iss.14; pg.1820, 8 pgs.) as applied to claims 1-7 above and further in view of Boyer et al (5,907,493).

(A) As per claim 8, Walker and Szilagyi disclose the method of tracking immunizations (See Walter, Col.4, lines 34-58).

The combination of Walker and Szilagyi do not explicitly disclose wherein the immunization product packaging is a vial.

However, this feature is known in the art, as evidenced by Boyer. In particular, Boyer suggests wherein the immunization product packaging is a vial (See Boyer, Col.9, lines 20-33).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Boyer within the combined teachings of Walker

and Szilagyi with the motivation of providing optimum efficiency of pharmacy operations, dependent upon certain parameters: (1) a proximity to a predetermined packaging /shipping locations; (2) the probability of future drug access at a predetermined inventory storage location; (3) the size of separately-addressable storage locations; and (4) the location of confusingly similar drugs or dosages (See Boyer, Col.4, lines 2-10).

(B) As per claim 9, Boyer discloses the method of tracking immunizations wherein the immunization product packaging is a package comprising a plurality of vials (See Boyer Fig.1, Col.6, lines 17-31).

The motivation for combining the respective teachings of Walker, Szilagyi and Boyer are as discussed above in the rejection of claims 1 and 8, and incorporated herein.

(C) As per claim 10, Boyer discloses the method of tracking immunizations wherein the immunization product packaging is a syringe (Examiner interprets drugs or dosages to be a form of syringe See Boyer, Col.4, lines 1-10).

The motivation for combining the respective teachings of Walker, Szilagyi and Boyer are as discussed above in the rejection of claims 1 and 8, and incorporated herein.

(D) As per claim 11, Boyer discloses the method of tracking immunizations of claim 1 wherein the immunization product packaging is a package composing a plurality of

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syringes (Examiner interprets drugs or dosages to be a form of syringe See Boyer, Col.4, lines 1-10).

The motivation for combining the respective teachings of Walker, Szilagyi and Boyer are as discussed above in the rejection of claims 1 and 8, and incorporated herein.

(E) As per claim 12, Boyer discloses the method of tracking immunizations wherein at least a portion of the immunization-tracking file is uploaded into a computerized patient file maintained at a medical provider facility (See Boyer, Col.5, lines 36-58).

The motivation for combining the respective teachings of Walker, Szilagyi and Boyer are as discussed above in the rejection of claims 1 and 8, and incorporated herein.

(F) As per claim 13, Szilagyi discloses the method of tracking immunizations wherein at least a portion of the immunization-tracking file is uploaded into a computerized patient-billing file maintained at a medical provider facility (See Szilagyi, Page 2, Paragraph 5; Page 7, Paragraphs 7- Page 8, Paragraph 6).

The motivation for combining the respective teachings of Walker, Szilagyi and Boyer are as discussed above in the rejection of claims 1 and 8, and incorporated herein.

(N) As per claim 14, Szilagvi discloses the method of tracking immunizations wherein at least a portion of the immunization-tracking file is uploaded into a computerized patient medical insurance file maintained at a medical provider facility (See Szilagyi, Page 7; Paragraphs 7- Page 8, Paragraph 6).

The motivation for combining the respective teachings of Walker, Szilagyi and Boyer are as discussed above in the rejection of claims 1 and 8, and incorporated herein.

(O) As per claim 15, Walker discloses the method of tracking immunizations wherein the communications device comprising machine-readable data is attached to the immunization product packaging at an immunization product manufacturer's location (Col.2, lines 49-63).

(P) As per claim 16, Boyer discloses the method of tracking immunizations wherein the network is assessable by an immunization-tracking authority comprising a computer facility connected to the network for retrieving and processing of said plurality of computerized immunization-tracking files on the network (Col.10, lines 1-60).

(Q) As per claim 17, Walker discloses a method of tracking immunizations by use of machine-readable communications devices, the method composing the steps of: attaching a machine-readable communications device on an immunization product

package (Col.4, lines 34-58), the communications device comprising machine-readable data including immunization product identification, manufacturer identification, immunization product lot number, and manufacturing date (Col.4, lines 34-58).

Walker does not explicitly disclose entering at least a portion of the machine-readable data read by a machine from the machine-readable communications device on the immunization product package and additionally entering patient identification and administration date to define a provider's immunization-tracking file on a provider's computer at an immunization provider location.

However, these features are known in the art, as evidenced by Szilagyi. In particular, Szilagyi suggests entering at least a portion of the machine-readable data read by a machine from the machine-readable communications device on the immunization product package and additionally entering patient identification and administration date to define a provider's immunization-tracking file on a provider's computer at an immunization provider location (See Szilagyi, Page 8, Paragraphs 1-5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Szilagyi within the system of Walker with the motivation of providing patient reminder systems in primary care settings which are effective in improving immunizations rates. Primary care physicians should use patient reminders to improve immunization delivery (See Szilagyi, Page 2, Paragraph 1).

(R) As per claim 18, Szilagyi discloses the method of tracking immunizations composing a plurality of provider's computers connected to an immunization-tracking

network, said plurality of provider's computers comprising a plurality of provider's immunization-tracking files (Page 8, Paragraphs 1-4).

(S) As per claim 19, Szilagy discloses the method of tracking immunizations wherein the immunization- tracking network is accessible by an immunization-tracking authority comprising a computer facility connected to the immunization-tracking network for retrieving and processing of said plurality of provider's immunization-tracking files on the immunization-tracking network (Page 8, Paragraphs 1-4).

(T) As per claim 20, Szilagy discloses the method of tracking immunizations comprising a manufacturer's immunization product file composing the machine-readable data on a manufacturer's computer, the manufacturer's computer being connected to the immunization-tracking network accessible by the immunization-tracking authority (Page 8, Paragraphs 1-4).

(U) As per claim 21, Walker discloses a method of medical tracking by use of machine-readable communications devices, the method comprising the steps of:
attaching a machine-readable communications device on a medical product package, the communications device comprising machine-readable data including at least one of a medical product identification, manufacturer identification, product lot number, and manufacturing date (See Walker, Col.4, lines 34-58).

Walker does not explicitly disclose entering at least a portion of the machine-readable data read by a machine from the machine-readable communications device on the medical product package to a computerized medical product tracking file at a provider location; and entering patient identification and administration data on the tracking file generally at the time of administration.

However, these features are known in the art, as evidenced by Szilagyi. In particular, Szilagyi suggests that the method having entering at least a portion of the machine-readable data read by a machine from the machine-readable communications device on the medical product package to a computerized medical product tracking file at a provider location (See Szilagyi, Page 8, Paragraphs 1-5); and entering patient identification and administration data on the tracking file generally at the time of administration (See Szilagyi, Page 8, Paragraphs 1-5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Szilagyi within the system of Walker with the motivation of providing patient reminder systems in primary care settings which are effective in improving immunizations rates. Primary care physicians should use patient reminders to improve immunization delivery (See Szilagyi, Page 2, Paragraph 1).

(V) As per claim 37, Walker discloses a method of medical tracking by use of machine-readable communications devices, the method comprising the steps of:

attaching a machine-readable communications device on a medical product, the communications device comprising machine-readable data including at least one of a

product identification, manufacturer identification, product lot number, and manufacturing date (See Walker, Col.4, lines 34-58).

Walker does not explicitly disclose that the method having entering at least a portion of the machine-readable data read by a machine from the machine-readable communications device on the product and additionally entering patient identification and administration data to define a provider's tracking file on a provider's computer at a provider location (See Szilagyi, Page 8, Paragraphs 1-5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Szilagyi within the system of Walker with the motivation of providing patient reminder systems in primary care settings which are effective in improving immunizations rates. Primary care physicians should use patient reminders to improve immunization delivery (See Szilagyi, Page 2, Paragraph 1).

(W) As per claim 41, Walker discloses a system for medical tracking by use of machine-readable communications devices, the system comprising:

a machine-readable communications device attached to a medical product, the communications device comprising machine-readable data including at least one of a medical product identification, manufacturer identification, product lot number, and manufacturing date (See Col.4, lines 34-58).

Walker does not explicitly disclose that the system having a computerized tracking file at a provider location for entering at least a portion of the machine-readable

data read by a reader from the machine-readable communications device on the medical product and for entering patient identification on the tracking file.

However, these features are known in the art, as evidenced by Szilagyi. In particular, Szilagyi suggests that the system having a computerized tracking file at a provider location for entering at least a portion of the machine-readable data read by a reader from the machine-readable communications device on the medical product and for entering patient identification on the tracking file (See Szilagyi, Page 8, Paragraphs 1-5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Szilagyi within the system of Walker with the motivation of providing patient reminder systems in primary care settings which are effective in improving immunizations rates. Primary care physicians should use patient reminders to improve immunization delivery (See Szilagyi, Page 2, Paragraph 1).

(X) As per claim 56, Walker discloses a system for medical tracking by use of machine-readable communications devices, the system comprising:

a machine-readable communications device on a medical product package, the communications device comprising machine-readable data including at least one of the product identification, manufacturer identification, product lot number, and manufacturing data (See Walker, Col.4, lines 34-58).

Walker does not explicitly disclose that the system having a provider's computer at a provider location for entering at least a portion of the machine-readable data read

by a machine from the machine-readable communications device on the product package and additionally entering patient identification to define a provider's tracking file.

However, these features are known in the art, as evidenced by Szilagyi. In particular, Szilagyi suggests that the system having a provider's computer at a provider location for entering at least a portion of the machine-readable data read by a machine from the machine-readable communications device on the product package and additionally entering patient identification to define a provider's tracking file (See Szilagyi, Page 8, Paragraphs 1-5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Szilagyi within the system of Walker with the motivation of providing patient reminder systems in primary care settings which are effective in improving immunizations rates. Primary care physicians should use patient reminders to improve immunization delivery (See Szilagyi, Page 2, Paragraph 1).

(Y) Claims 22-36, 38-40, 42-55 and 57-58 recite the underlying process steps of the elements of claims 1-20 respectively. As the various elements of claims 1-20 have been shown to be either disclosed by or obvious in view of the collective teachings of X and Y, it is readily apparent that the apparatus disclosed by the applied prior art performs the recited underlying functions. As such, the limitations recited in claims 22-36, 38-40, 42-55 and 57-58 are rejected for the same reasons given above for method claims 1-20, and incorporated herein.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied art disclose medical data draft for tracking and evaluating medical treatment (5,324,077), system for tracking and dispensing medical items (5,912,818) and system and method for drug management (6,021,392).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanel Frenel whose telephone number is 571-272-6769. The examiner can normally be reached on Monday-Thursday from 6:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

V.F
V.F



JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER